

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL CLASS ACTIONS

**PLAINTIFFS' SUR-REPLY IN OPPOSITION TO CONSOLIDATED MOTION TO
DISMISS THE AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

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I. INTRODUCTION

Defendants' replies suffer from three common defects. They (i) ignore controlling allegations of the complaint; (ii) ignore the Court's May 13, 2003 Order ("Order"); and (iii) assert a host of factual issues that are inappropriate at this stage of the proceedings.

For example, Defendants repeatedly assert that there is no incentive to engage in the AWP Inflation Scheme in the generic and multiple source drug market. However, the AMCC's controlling allegations expressly aver the reasons why AWP inflation occurs for generic and multiple source drugs and provides specific allegations that AWP inflation in the generic marketplace is rampant; cites specific instances where generic drug manufacturers have acted to meet the AWP inflated prices of others who inflate their AWP's; and alleges that one manufacturer has admitted in litigation elsewhere that it competes with other Defendants on the basis of AWP inflation and, when prevented from doing so, immediately lost business. Thus, the AMCC establishes that the AWP Inflation Scheme involves generic and multiple source manufacturers. All of these allegations are either ignored or quarreled with in the dozens of pages submitted on this issue in Defendants' common brief and in the Defendant-specific briefs. *See* Section II.E.

In addition to ignoring the AMCC's allegations, Defendants' common tactic in their 9(b) motions is to raise the pleading bar by demanding specifics not sought in their prior motions to dismiss. Plaintiffs crafted their AMCC to comply with the Court's May 13 Order, yet Defendants' replies completely ignore the terms of the Order as if it did not exist and seek to impose new pleading requirements not required by the Order or by Rule 9(b). For example, Defendants now assert that Plaintiffs must identify in the complaint "communications" between union health funds and PBMs. But Defendants do not proffer any explanation as to why such communications are required under Rule 9(b) or how they would enlighten Defendants as to the "who, what, when and where" of the AWP Inflation Scheme as implemented by Defendants in the PBM marketplace. Defendants also now demand additional details that would be known

only to parties to the scheme, ignoring the AMCC's allegations that those details, such as Defendants' real AWP or the secret rebates provided to PBMs, are closely guarded "state secrets" that are not in Plaintiffs' possession. As another example, Defendants' initial motion to dismiss – filed almost a year ago – did not suggest that Plaintiffs needed to allege precise spreads for every drug and every time period, but that is now the level of pleading detail that Defendants emphatically demand is needed to comply with Rule 9(b).

Defendants' attacks on the RICO Counts also ignore the allegations and factual changes made in response to the Order. First, Defendants cannot hide from the fact that the AMCC solves the Court's "hub and spoke" concern. Second, the AMCC adds factual allegations that explain the structure of the enterprises and identify a shared common purpose in both the PBM and publisher enterprises. These factual allegations directly address the Court's concerns regarding common purpose and participation in an enterprise. Though Defendants call these allegations "ritualistic," they are in fact the type of factual allegations that satisfy RICO pleading standards in this Circuit, particularly where the facts are exclusively in Defendants' possession.

One Defendant has called the AWP Inflation Scheme "scandalous, or worse, fraudulent." ¶ 319.¹ Another has confessed to the "deliberate manipulation of AWP or WAC prices as a problem that we need to address." ¶ 277. Defendants maintain that not only is the "scandalous" practice not subject to RICO, it is also free from challenge under any of the state consumer protection laws identified in the AMCC. Fortunately for consumers and payors who are the victims of this scandal, state consumer laws do allow for redress. Defendants' claim that Plaintiffs fail to plead causation under state consumer protection laws is rejected by Defendants' own documents cited in the AMCC acknowledging that third-party payors and co-payors are the direct targets of AWP manipulation. Plaintiffs have thus alleged causation. Furthermore, consumer protection laws do not require reliance as Defendants assert, and each Plaintiff has standing to bring claims under the consumer protection claims.

¹ "¶" denotes paragraphs in the AMCC.

Finally, Defendants' protestations to the contrary, another state law that allows redress for this "deliberate manipulation" of AWP's is the law of civil conspiracy. The allegations concerning the agreements and acts between PBMs and Defendants, and between the Publishers and Defendants, all committed to achieve an improper and unlawful purpose, present a textbook claim of civil conspiracy.

Defendants' motions should be dismissed in their entirety.

II. ARGUMENT

A. A Generalized Scheme To Defraud Supported By Specific Allegations Directed Against Each Defendant Satisfies Rule 9(b)

1. The Defendants' Ever-Increasing 9(b) Demands are Not Supported by the Law or the Court's Prior Order

From the filing of their original motion to dismiss the MCC, to their recent reply briefs directed to the AMCC, Defendants present escalating and changing demands as to the requirements of Rule 9(b). They demand that the AMCC contain details not requested before, including information that would serve no purpose under Rule 9(b), such as the terms of contracts between PBMs and union health plans, which terms are not germane to the claims of whether PBMs and Defendants joined in a scheme to defraud, as well as a host of other pleading requirements that this Court did not specify in its May 13 Order. *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) ("*AWP*"). Defendants also continue to ignore that their 9(b) motions directed to the MCC, which alleged the PBM's role in the AWP Inflation Scheme, were denied, except for three specific criteria required by the Court of any future complaint, with which the AMCC complies. *Id.* at 194.

a. The PBM allegations satisfy Rule 9(b)

In an effort to convince the Court that the PBM allegations are deficient, Defendants either ignore the allegations or distort them. First, Defendants completely ignore the fact that the PBM allegations were included in the MCC, as recognized by the Court's May 13 Order:

Plaintiff union and employee health benefit plans contract with drug plan managers, known as Pharmacy Benefit Managers (“PBMs”), which operate as intermediaries between the pharmaceutical companies and the private health plans. These PBMs set prices on their formularies – their drug fee lists – based on the AWP figures reported in the same trade publications used by the Medicare program, less a certain percentage discount. Again, defendants market the same pricing and reporting “spread” to PBMs that they do to individual health care providers serving Medicare patients. The PBMs are offered drugs at highly “discounted” actual prices while charging the private health plans fees based on the inflated AWP. The PBMs benefit by keeping the “spread” for themselves and the pharmaceutical companies benefit because PBMs are drawn to keeping on their formularies drugs from those companies offering the most lucrative “spreads.”

AWP, 263 F. Supp. 2d at 179-80. Significantly, the Court did not require any more details regarding the role of the PBMs in the AWP Inflation Scheme. Rather, with respect to the scheme as alleged in both the Part B and PBM markets, the Court directed that the complaint identify (i) the drugs purchased from a Defendant, (ii) the fraudulent AWP for each drug, and (iii) a purchaser. The AMCC complies with each of these directives and consequently complies with Rule 9(b).

Implicitly recognizing that the AMCC complies with the Court’s May 13 Order, Defendants change course and now demand information not previously demanded in their Rule 9(b) motions directed at the PBM part of the case, such as “communications” between union health care plans and PBMs.² Defs. Reply at 4. Yet Defendants do not explain how these communications are relevant to the claims in the AMCC, particularly in light of the Court’s recognition that Plaintiffs alleged that the drug companies market the “spread,” while the PBMs “keep[] the ‘spread’ for themselves.” *AWP*, 263 F. Supp. 2d at 180. Nor do Defendants explain why such communications are required under 9(b).

² In their individual memoranda, Defendants seek to impose a host of other requirements. For example, AstraZeneca in its Defendant-“specific” brief demands that there must be allegations as to the pricing, sale, marketing and limitations of each drug. AstraZeneca at 2. Other Defendants demand that the complaint identify the prices each Plaintiff paid in every transaction, and still others demand that the AMCC identify competing drugs (e.g., Abbott, Tap). Such demands would eviscerate Rule 8(a) and have never been imposed by any court. The Court has recognized that, if left to their own devices, Defendants’ demands will never cease. That is why the May 13 Order provided a standard that was sensible and objective. The AMCC meets that standard.

Second, Defendants' replies continue to completely ignore authorities holding that, where the facts are exclusively in Defendants' possession, a high degree of pleading precision is not required; rather, Plaintiffs need only present a general outline of the scheme. *See* Plaintiffs' Opp. at 10-12 (citing, among other cases, this Court's decision in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001)). Defendants seek to avoid these authorities by arguing that the details of their secret rebates and spread arrangements with PBMs are not in their exclusive control, but this argument is spurious and contrary to the allegations of the AMCC. The negotiations and agreements between Defendants and PBMs are closely guarded secrets to which union health care plans are not a party,³ and Defendants do not suggest otherwise. Thus, unlike *United States ex. rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (cited by Defendants), Plaintiffs here are in no position to uncover all of the details of the frauds or to plead them in the specificity now demanded.

Defendants next try to confuse the issue by claiming that Plaintiffs' "various allegations" regarding Part B drugs do not satisfy 9(b) with respect to PBM claims because they involve "hundreds of different drugs sold through retail pharmacies" that are reimbursed on different contracts. Defs. Reply at 3. However, as the Court recognized in its May 13 Order, the scheme is essentially the same whether within or outside the Part B context. AWP is used as a tool to encourage providers in the case of Part B covered drugs, or PBMs in the case of non-Part B drugs, to utilize a specific drug and an inflated AWP in order to benefit from the spread. *AWP*, 263 F. Supp. 2d at 178-82. And Defendants are dead wrong when they state the "AMCC is devoid of any defendant-or-drug-specific allegations relating to the PBM claims." Defs. Reply at 3. In other words, the drugs at issue are not just sold in the Part B market; they are also used by practitioners in the treatment of non-Part B patients. And once a fraudulent AWP is published, that fraudulent AWP is used as a reimbursement benchmark in all markets. *See, e.g.*, ¶ 168. The allegations in the AMCC on any given drug supply the specificity for both the Part B

³ *See* ¶ 175 ("PBMs pocket a secret spread"); ¶¶ 191-97 (outlining concealment).

and PBM markets. And, as required by the May 13 Order, each non-Part B drug listed in Appendix A is specified by the AMCC to be fraudulent in both the Part B and PBM context. Again, nothing more is required by Rule 9(b).

Finally, Defendants chastise Plaintiffs for attempting to “hide behind the massive case they have created as a reason to disregard Rule 9(b).” Nonsense; even if the case involved one Defendant, the pleading requirements would be the same and would be satisfied by the AMCC. Defendants originally demanded the “who, what, when and how” of the fraud, and the AMCC supplies that information. In the context of the PBM involvement in the AWP Inflation Scheme, every Defendant is on notice of the nature of the scheme and the precise drugs at issue. The remaining details now demanded by Defendants are matters properly left to discovery (*e.g.*, what Plaintiffs paid for each drug), or matters that could only be pled if Plaintiffs were involved in or participated in the fraud.⁴ Defendants did not raise these issues in their original motions, and the issues are not properly raised now *after* the Court instructed Plaintiffs how to satisfy Rule 9(b) in repleading. And to the extent that any of the issues were inferentially contained in Defendants’ prior motions, they were rejected by the Court.

b. Plaintiffs have satisfied Rule 9(b) as to Part B drugs

Defendants again ignore the controlling allegations and the Court’s May 13 Order. The controlling allegations clearly identify at issue not “all Part B covered drugs” as Defendants claim, but those identified in Appendix A. *See* ¶ 11; *see also, e.g.*, ¶¶ 201, 231, 250, etc., for each Defendant. And, most importantly, the Part B allegations comply precisely with the Court’s directive to plead three elements: (i) the specific drug purchased from a Defendant, (ii) the allegedly fraudulent AWP, and (iii) the identity of the Plaintiff that purchased the drug. *AWP*, 263 F. Supp. 2d at 194.

⁴ Several Defendants also demand details of Plaintiffs’ purchase prices. Such purchase information is not required and would turn the AMCC into a thousand page encyclopedia. Plaintiffs have alleged that they purchased drugs based on inflated AWP’s (¶ 139), and that satisfies 9(b).

c. The allegations of hidden paybacks, rebates, educational grants and similar payoffs are sufficient

Defendants claim that the allegations of improper inducements also violate 9(b). Again, the Court did not require any further details regarding improper inducements, so it is hard to conceive how the allegations that survived the motions directed to the MCC, and which were actually improved upon in the AMCC, “blatantly violate” Rule 9(b) as Defendants now claim.

B. Plaintiffs’ RICO Allegations Should Be Sustained

As previously asserted, Count I of the AMCC properly alleges 66 separate association-in-fact Manufacturer-Publisher Enterprises, with each enterprise consisting of a single pharmaceutical company and a single publisher.⁵ ¶¶ 624, 628; *see also* Plaintiffs’ Opp. at 19. Count II properly alleges 88 separate association-in-fact Manufacturer-PBM Enterprises, with each enterprise consisting of a single pharmaceutical company and a single PBM. ¶¶ 650, 661; *see also* Plaintiffs’ Opp. at 25. These reconstituted association-in-fact RICO enterprises solve the “hub-and-spoke” infirmity that the Court flagged in dismissing civil RICO claims from the previous complaint alleging the existence of the “AWP Enterprises” and the “Publisher Enterprises.” *AWP*, 263 F. Supp. 2d at 172.

In reply, Defendants level a variety of attacks against the sufficiency of the AMCC’s RICO enterprise allegations and Plaintiffs’ standing to bring RICO claims. *See* Defs. Reply at 6-13. However, Defendants’ pleading challenges ignore the detailed allegations of Counts I and II and well-settled First Circuit authority (and other persuasive cases) demonstrating the sufficiency of Plaintiffs’ RICO counts.

⁵ Defendants chastise Plaintiffs as to the number of separate enterprises, as if numbers are a measure of pleading sufficiency. If Plaintiffs sued each Defendant in a standalone case, there would be seven enterprises in the case – three publisher enterprises and four PBM enterprises. This is hardly a number that suggests some type of pleading deficiency. The fact that there are dozens of enterprises simply reflects the consolidation by the MDL Panel of these cases.

1. The AMCC Properly Alleges the Enterprise Structures

Defendants attack Plaintiffs for engaging in a “cynical pleading game” by purportedly failing to set forth a “single fact” supporting the enterprise allegations. Defs. Reply at 6-10. Defendants’ unhelpful rhetoric aside, *actually reviewing* the AMCC and the proper pleading standards – in lieu of leveling sweeping and unfounded assaults – reveals the sufficiency of Plaintiffs’ enterprise allegations.

Contrary to Defendants’ assertion, *see* Defs. Reply. at 7, “there is no heightened pleading standard for allegations of RICO enterprise ‘At the pleading stage, a plaintiff typically need only identify the alleged enterprise to satisfy notice pleading requirements.’” *Grider v. Keystone Health Plan Cent., Inc.*, 2003 U.S. Dist. Lexis 16551, at *69 (E.D. Pa. Sept. 18, 2003) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 790 (3d Cir. 1984)). In that recent case, the plaintiff physician and her professional corporation provided medical services to about 4,000 patients who were insureds of defendant Keystone Health Plan Central, an HMO. In their civil RICO claim, plaintiffs alleged that Keystone, two entities (Capital Blue Cross and Hallmark) that controlled Keystone, and the CEOs of those three corporate entities, and “various non-parties [software providers, claims reviewers and trade associations] together form[ed] what is styled as the ‘Managed Care Enterprise’, an entity which allegedly operates to defraud plaintiffs and other physicians” by wrongfully delaying and denying compensation. *Id.*, at *4-6, 66. In their motion to dismiss, defendants contended that plaintiffs did not “plead[] a RICO enterprise or its structure with sufficient detail.” *Id.*, at *67.

Rejecting defendants’ arguments, the court observed that plaintiffs had identified each entity that comprised the Managed Care Enterprise and “describe[d] how defendants allegedly use nonparty firms to further the RICO violations, employing such devices as ‘common billing forms, a technology alliance and central coordination to accomplish their systematic scheme to deny, delay and diminish payments to plaintiffs.’” *Id.*, at *68-69 (record references omitted). As in this case, the defendants in *Grider* contended that “ordinary business relationships or

contractual relationships do not suffice for enterprise allegations.” *Id.* The court rejected that contention, however, stating:

[P]laintiffs allege that the relationships between the defendants and the other entities that make up the enterprise go beyond ordinary business dealings. While greater specificity with respect to structure and the interrelationship between the portions of the alleged enterprise would no doubt be desirable, *it is uncertain how plaintiffs could accomplish this without discovery.... Plaintiffs here have identified the parties that make up the enterprise, described how these parties may be associated (through financial incentives, for example); and alleged in sufficient detail for notice pleading that the entities form a continuing unit with a common course of conduct.*

Id., at *69-70 (emphasis added).

The RICO enterprise allegations in Counts I and II of the AMCC more than satisfy the applicable pleading standards, as elucidated by the *Grider* court and as set forth in other recent, persuasive district court opinions. *See* ¶¶ 624, 627, 628(a)-(v), 635-36, 650, 652, 653-54, 657-59, 661(a)-(v); *see also Panix Promotions, Ltd. v. Lewis*, 2002 U.S. Dist. Lexis 784, at *17 (S.D.N.Y. Jan. 17, 2002) (holding that boxer Lennox Lewis sufficiently alleged an association-in-fact enterprise consisting of his promoter, his lawyer, his manager and his financial advisor, which “evinces a ‘continuity of structure’”); *R.J. Reynolds Tobacco Co. v. S K Everhart, Inc.*, 2003 U.S. Dist. Lexis 13440, at *11 (M.D.N.C. July 31, 2003) (defendants conceded that tobacco manufacturer Reynolds had properly pled an enterprise consisting of “Reynolds along with various wholesalers ... and various retailers ... [that] formed an ‘association-in-fact’ through their marketing relationships”; “The complaint describes that this association-in-fact had a ‘unity of purpose: to promote R.J. Reynolds cigarettes to consumers in order to increase R.J. Reynolds’ market share among adult smokers, while simultaneously increasing adult smoker traffic in retailers’ stores.’”).

The AMCC presents all of the *facts* necessary to allege an ongoing, continuing enterprise. The *participants* are a manufacturer on one hand, and a Publisher or PBM on the other. ¶¶ 624, 651. The *structure* of each enterprise is simple. In the case of each

Manufacturer-Publisher Enterprise, the participants “agree[d] to a structure wherein the manufacturers made decisions as to what AWP’s would be reported.” ¶ 627. A “common communication network” exists through “which the Defendant Drug Manufacturer and the specific Publisher share information on a regular basis” by, typically, “a manufacturer ... instruct[ing] a publisher to list a certain AWP.” ¶ 625. Try as they may, Defendants cannot demonstrate that the Publishers made a unilateral decision not to survey actual sales prices in the market. Defs. Reply at 9. As the AMCC explains, the manufacturer sits atop the structure and mandates the AWP’s to be reported, and the Publishers report them as mandated. ¶¶ 627, 635-36. Furthermore, the AMCC now alleges that the participants shared a common purpose benefiting both principal parties: (i) Defendants get to control AWP’s in order to create spreads and push product, and (ii) the Publishers increase their profit margins through decreasing their costs of production by eliminating the need to independently obtain real and truthful AWP’s. ¶¶ 624, 626.

The structure and common communication network for the Manufacturer-PBM Enterprises are also adequately described in the AMCC. The AMCC explains in detail how each Defendant – sitting atop the enterprise – provides rebates and other inducements to each of the four PBMs in order to control the drugs that the PBMs place on their formularies and to otherwise encourage the PBMs to push Defendants’ products. As the AMCC alleges, each Defendant directed each PBM to base its contract pricing on AWP so that the Defendant could control drug pricing. In return for perpetuating the AWP Inflation Scheme, each Defendant provided to each PBM financial incentives including (i) access rebates for placement of products on the PBMs’ formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants in an effort to promote products. ¶¶ 653-58. The common purpose of the venture is manifest: increase the profits of the Defendant Drug Manufacturers (by selling more drugs) and the PBMs (through garnering spreads and collecting rebates) at the expense of Plaintiffs and the Class. ¶¶ 654-57. *None of these allegations are even addressed in*

Defendants' memoranda. See Defs. Reply at 9-10. ***And for good reason, as they establish a common and shared purpose at the pleading stage sufficient to defeat Defendants' motion.***

In sum, these factual allegations – which are not mere “ritualistic averments” as posited by Defendants – “identif[y] the parties that make up the enterprise, describe[] how these parties may be associated (through financial incentives, for example); and allege[] in sufficient detail for notice pleading that the entities form a continuing unit with a common course of conduct.”

Grider, 2003 U.S. Dist. Lexis 16551, at *70. The allegations need not be lengthy and complex to meet this standard. Plaintiffs have plainly alleged enterprises that “exhibit structural continuity which exists where there is an organizational pattern or system of authority that provides a mechanism for directing the group’s affairs on a continuing, rather than an ad hoc, basis.” *Manhattan Telecomms. Corp. v. DialAmerica Mktg.*, 156 F. Supp. 2d 376, 381-82 (S.D.N.Y. 2001). And, these factual allegations meet the First Circuit requirement of a “common purpose” and “systematic linkage” as also evidenced by allegations of financial ties and continuing coordination. *Libertad v. Welch*, 53 F.3d 428, 444 (1st Cir. 1995).⁶

Defendants cannot wish away these allegations. Nor can they impose a higher pleading standard that would require Plaintiffs to have substantial “inside” knowledge of all aspects of the enterprises’ operations – an impossible standard proffered by *no* case cited by Defendants. The Court should reject Defendants’ challenge to the enterprises alleged in the AMCC.

2. The AMCC Properly Alleges that Defendants Conducted the Affairs of the Manufacturer-Publisher Enterprises and the Manufacturer-PBM Enterprises

As highlighted in Plaintiffs’ opposition brief, Counts I and II allege that Defendants violated Section 1962(c) of RICO by conducting the affairs of the Manufacturer-Publisher Enterprises and the Manufacturer-PBM Enterprises through a pattern of racketeering activity, thereby satisfying the standard established by the Supreme Court in *Reves v. Ernst & Young*, 507

⁶ If the Court is still not convinced as to the adequacy of the RICO Counts due to a lack of specificity, then given the adequacy of the AMCC, the Court should allow discovery. See Plaintiffs’ Memorandum In Support Of Motion To Take Additional Limited Discovery.

U.S. 170, 179 (1983) (stating the plaintiff must allege that defendant played “*some* part in directing the enterprise’s affairs”) (emphasis in original); *see also Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1559 (1st Cir. 1994) (the “operation or management test” established in *Reves* requires only “a degree of direction,” which can be direct or indirect); Plaintiffs’ Opp. at 28-32.

In response, Defendants contend that “Plaintiffs have not alleged any facts explaining how any one of the defendants exerted control over independent publishers and PBMs.” Defs. Reply at 11. Defendants are wrong. As the AMCC explains, Defendants controlled each of their Manufacturer-Publisher Enterprises by making decisions as to what AWP’s would be reported and issuing instructions on how its AWP’s were to be reported. *See* ¶¶ 627, 635-36. The Publishers themselves have confirmed this by stating that all pricing information is supplied by the Defendants without independent review. ¶ 136. ***And it is important to keep in mind that Defendants are under no legal obligation to report AWP’s or even use the Publishers but chose to do so to further their AWP Inflation Scheme through the RICO enterprise; therefore, the AMCC plainly alleges control that goes well beyond the “arms-length relationships” that Defendants spin.*** *See* Defs. Reply at 11.

Each Defendant also controls and otherwise participates in the affairs of its respective Manufacturer-PBM Enterprises by (i) directly controlling the price for its AWPIDs, which determines the amount of spread each of the PBMs’ receives as part of its compensation, ¶ 667(a), (ii) “directly control[ing] the creation and distribution of marketing, sales, and other materials used to inform each of the PBMs of the profit potential of its AWPIDs, ¶ 667(d), and (iii) providing rebates or other inducements to place a certain Defendant Drug Manufacturer’s AWPIDs on a PBM formulary or advocate the use of a certain AWPID, ¶ 667(f) (specifically listing the various forms of rebates and inducements). *See also* Plaintiffs’ Opp. at 28-32.

Defendants apparently believe that Plaintiffs must plead all of the details comprising the totality of the command and control structure of the enterprises, but this is not the proper

standard. To the contrary, Rule 9(b) does not apply to allegations of Section 1962(c)'s "conduct" element. *See, e.g., R.J. Reynolds*, 2003 U.S. Dist. Lexis 13440, at *20 ("The complaint alleges that [defendant] Terrell 'operated the scheme.' Such an allegation is sufficient to satisfy the 'operation or management' test.").

Defendants' reply also advances the misimpression that Defendants must control *all* aspects of the enterprises' affairs before being subject to liability. Yet controlling authorities maintain that liability under Section 1962(c) is *not* limited to upper management, and that the operation or management requirement will be satisfied "by lower rung participants in the enterprise who are under the direction of upper management" provided that that they at least participate in some manner in the operation and management of the enterprise. *See, e.g., Reves*, 507 U.S. at 184-85. Consequently, courts have recognized that the level of participation that may result in RICO liability "depends on the nature and configuration of the enterprise and the defendant's position in or connection to the enterprise." *Dale v. Frankel*, 131 F. Supp. 2d 852, 858 (S.D. Miss. 2001). Importantly, the First Circuit has observed that "Congress intended to reach all who participate in the conduct of that enterprise, *whether they are generals or foot soldiers*." *United States v. Oretto*, 37 F.3d 739, 751 (1st Cir. 1994) (emphasis added; footnote omitted).⁷ *See also MCM Partners, Inc. v. Andrews-Bartlett & Assocs.*, 62 F.3d 967, 979 (7th Cir. 1995) (When the alleged enterprise is an association-in-fact, even lower-rung participants ("foot soldiers") who have "knowingly implemented management's decisions," thereby enabling the enterprise to achieve its goals, may be held liable); *Goren v. New Vision Int'l, Inc.*, 156 F.3d 721, 728 n.3 (7th Cir. 1998) (holding that "lower rung" members of an alleged association-in-

⁷ In upholding the RICO convictions of mere "collectors" for a loansharking ring, the First Circuit carefully parsed *Reves* and emphasized that the accountants in *Reves* were not liable because they "neither made those decisions nor carried them out; in other words, the accountants were outside the chain of command through which the enterprise's affairs were conducted." *Id.* at 750. The court also emphasized that "[s]pecial care is required in translating *Reves*' concern with 'horizontal' connections – focusing on the liability of an outside advisor – into the 'vertical' question of how far RICO liability may extend within the enterprise but down the organizational ladder." *Id.* Indeed, citing *Oretto* and other First Circuit decisions following *Oretto*, the court in *United States v. Owens*, 167 F.3d 739, 754 (1st Cir. 1999), stated that "*Reves*'s analysis does not apply where a party is determined to be *inside* a RICO enterprise." (Emphasis added; citations omitted.)

fact enterprise may be found liable “because they ... knowingly implemented the decisions of upper management and thereby participated in the direction of the enterprise”).

Of course, the AMCC alleges that Defendants *are* the leaders of their respective association-in-fact enterprises, while the Publishers and PBMs are not. *See* ¶¶ 625, 627, 635-36, 653, 667. Thus, the AMCC clearly alleges that Defendants are the “generals” of these enterprises. *Oreto*, 37 F.3d at 751. But even if the reverse were true – that the Publishers and PBMs were the “generals” and the pharmaceutical manufacturers were the “foot soldiers” – Defendants would still be liable for conducting the enterprises’ affairs.

In light of the AMCC’s very specific factual allegations of control *and the First Circuit precedents cited* and discussed above, it is surprising that Defendants continue to rely *solely* upon a district court outside the First Circuit, *Arrandt v. Steiner*, 2001 U.S. Dist. Lexis 11410 (N.D. Ill. Aug. 3, 2001). *See* Defs. Reply at 11. As Plaintiffs explained in their opposition brief, *Arrandt* does not apply here given the contrast between the substantial allegations of control set forth in the AMCC and the *Arrandt* defendant’s total lack of participation in, let alone control of, the alleged enterprises. Indeed, the *Arrandt* plaintiff’s complaint did not even identify by name all of the members of the alleged association-in-fact enterprise, let alone the roles that each of them played in the alleged scheme to defraud the customers. Defendants can only try to make *Arrandt* apply to this case by ignoring entire paragraphs of the AMCC that explain how Defendants control the respective enterprises. *See* Plaintiffs’ Opp. at 29 (citing ¶¶ 627, 635-36 and quoting ¶ 136), 30 (quoting ¶¶ 667(a) & (d)). Plaintiffs’ substantial allegations of control and participation should be sustained.

3. Plaintiffs Properly Allege that They Have Standing to Sue Defendants for RICO Violations

As previously stated, Plaintiffs’ allegations more than satisfy the “injury” and “causation” elements of a civil RICO claim brought under Section 1964(c) by alleging a direct connection between Defendants’ AWP Inflation Scheme, their alleged acts of mail and wire fraud, and the